

We Claim:

- 1 1. A process for preparing an oral dosage form containing modafinil, the
2 process comprising:
 - 3 forming a dosage form comprising
 - 4 about 7% - 25% by weight of modafinil particles have diameters
 - 5 greater than 220 µm; and
 - 6 about 75% - 93% by weight of modafinil particles have diameters
 - 7 less than 220 µm.
 - 1 2. The process according to claim 1 wherein about 7% by weight of the
2 modafinil particles have diameters greater than 220 µm and about 93% by weight of the
3 modafinil particles have diameters less than 220 µm.
 - 1 3. The process according to claim 1 wherein about 10% by weight of the
2 modafinil particles have diameters greater than 220 µm and about 90% by weight of the
3 modafinil particles have diameters less than 220 µm.
 - 1 4. The process according to claim 1 wherein about 15% by weight of the
2 modafinil particles have diameters greater than 220 µm and about 85% by weight of the
3 modafinil particles have diameters less than 220 µm.
 - 1 5. The process according to claim 1 wherein the specific surface area of the
2 modafinil particles is at least 0.2 m²/gm.
 - 1 6. The process according to claim 1 wherein the dosage form releases at least
2 75% of the modafinil in about 45 minutes.
 - 1 7. The process according to claim 1 wherein the dosage form comprises a
2 tablet or a capsule.
 - 1 8. The process according to claim 1 further comprising one or more
2 pharmaceutically acceptable excipients.
 - 1 9. The process according to claim 8 wherein the pharmaceutically acceptable
2 excipients comprise one or more of binders, diluents, disintegrants, surfactants, lubricants,
3 glidants, and coloring agents.
 - 1 10. The process according to claim 1 wherein forming the dosage form
2 comprises

3 blending the modafinil particles with one or more pharmaceutically inert excipients
4 to form a blend,
5 granulating the blend to form granules,
6 blending the granules with one or more pharmaceutically inert excipients, and
7 compressing or filling into a solid dosage form.

1 11. The process according to claim 10 wherein granulating comprises wet
2 granulation.

1 12. The process according to claim 10 wherein granulating comprises dry
2 granulation.

1 13. The process according to claim 10 wherein the dosage form comprises a
2 tablet and the process further comprises coating the tablet.

1 14. The process according to claim 1, wherein forming the dosage form
2 comprises blending the modafinil particles with one or more pharmaceutically inert
3 excipients to form a blend and compressing the blend or filling the blend into a solid
4 dosage form.

1 15. The process according to claim 1 wherein forming a dosage form further
2 comprises mixing the modafinil particles in geometric progression with one or more
3 pharmaceutically acceptable excipients to form a blend.

1 16. The process according to claim 15 further comprising:

2 granulating the blend to form granules;
3 optionally drying the granules;
4 sizing the granules;
5 mixing the sized granules with one or more pharmaceutically acceptable
6 excipients; and
7 compressing into a tablet.

1 17. An oral dosage form of modafinil comprising:
2 about 7% to 25% by weight of modafinil particles have diameters greater than 220
3 μm ; and

4 about 93% to 75% by weight of modafinil particles have diameters less than 220
5 μm.

1 18. The oral dosage form according to claim 17 wherein about 7% by weight of
2 the modafinil particles have diameters greater than 220 μm and about 93% by weight of
3 the modafinil particles have diameters less than 220 μm.

1 19. The oral dosage form according to claim 17 wherein about 10% by weight
2 of the modafinil particles have diameters greater than 220 μm and about 90% by weight of
3 the modafinil particles have diameters less than 220 μm.

1 20. The oral dosage form according to claim 17 wherein about 15% by weight
2 of the modafinil particles have diameters greater than 220 μm and about 85% by weight of
3 the modafinil particles have diameters less than 220 μm.

1 21. The oral dosage form according to claim 17 wherein the specific surface
2 area of the modafinil particles is at least 0.2 m²/gm.

1 22. The oral dosage form according to claim 17 wherein the dosage form
2 releases at least 75% of the modafinil in about 45 minutes.

1 23. The oral dosage form according to claim 17 wherein the dosage form
2 comprises a tablet or capsule.

1 24. The oral dosage form according to claim 17 further comprising one or more
2 pharmaceutically acceptable excipients.

1 25. The oral dosage form according to claim 24 wherein the pharmaceutically
2 acceptable excipients comprises one or more of binders, diluents, disintegrants,
3 surfactants, lubricants, glidants, and coloring agents.

1 26. A method of treating a condition using modafinil, the method of treating
2 comprising:

3 providing an oral dosage form of modafinil comprising
4 about 7% to 25% by weight of modafinil particles have diameters greater
5 than 220 μm; and
6 about 93% to 75% by weight of modafinil particles have diameters less
7 than 220 μm.

1 27. The method according to claim 25 wherein about 7% by weight of the
2 modafinil particles have diameters greater than 220 µm and about 93% by weight of the
3 modafinil particles have diameters less than 220 µm.

1 28. The method according to claim 25 wherein about 10% by weight of the
2 modafinil particles have diameters greater than 220 µm and about 90% by weight of the
3 modafinil particles have diameters less than 220 µm.

1 29. The method according to claim 25 wherein about 15% by weight of the
2 modafinil particles have diameters greater than 220 µm and about 85% by weight of the
3 modafinil particles have diameters less than 220 µm.

1 30. The method according to claim 25 wherein the specific surface area of the
2 total modafinil particles is at least 0.2 m²/gm.

1 31. The method according to claim 25 wherein the dosage form releases at least
2 75% of the modafinil in about 45 minutes.

1 32. The method according to claim 25 wherein the dosage form comprises a
2 tablet or capsule.

1 33. The method according to claim 25 further comprising one or more
2 pharmaceutically acceptable excipients.

1 34. The method according to claim 33 wherein the pharmaceutically acceptable
2 excipients comprise one or more of binders, diluents, disintegrants, surfactants, lubricants,
3 glidants, and coloring agents.

1 35. The method according to claim 25 wherein the condition comprises one or
2 more of narcolepsy and idiopathic hypersomnia.

1 36. An oral dosage form of modafinil comprising an intragranular portion and
2 an extragranular portion:

3 the intragranular portion comprising about 7% to 25% by weight of modafinil
4 particles having diameters greater than 220 µm, about 93% to 75% by weight of modafinil
5 particles having diameters less than 220 µm, and one or more pharmaceutically acceptable
6 excipients; and

7 the extragranular portion comprising one or more pharmaceutically acceptable
8 excipients.

1 37. The oral dosage form according to claim 36 wherein the oral dosage form
2 releases one or more of between 48% and 81% of the modafinil within 15 minutes,
3 between 68% and 87% of the modafinil within 30 minutes, between 76% and 95% of the
4 modafinil within 45 minutes, between 84% and 97% of the modafinil within 60 minutes,
5 and between 89% and 98% of the modafinil within 90 minutes.

1 38. The oral dosage form according to claim 37 wherein the modafinil is
2 released in a USP Apparatus II, in 900 ml of water, and stirred at 50 rpm.

1 39. The oral dosage form according to claim 36 wherein the oral dosage form is
2 provided with labeling for one or more of wakefulness promotion, to improve wakefulness
3 in patients with excessive daytime sleepiness associated with narcolepsy, and idiopathic
4 hypersomnia.